



1615 IFV

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

Mika JOKINEN et al.

Serial Number: 09/913,643

Group Art Unit: 1615

Filed: October 19, 2001

Examiner: Fubara, Blessing M.

For: BIODEGRADABLE CERAMIC FIBRES FROM SILICA SOLS

SUPPLEMENTAL REMARKS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

July 20, 2004

Sir:

These Remarks supplement the Preliminary Amendment filed May 6, 2004. Claims 1, 3-7, 16 and 18-33 are pending.

Claims 1, 3 and 4 recite a method for preparing a controllably biodegradable silica fiber by spinning the fiber from a spinning sol whose viscosity at a starting point for the spinning process is from about 1,000 to below 100,000 mPas, while claims 5-7 recite a method for preparing a controllably biodegradable silica fiber by spinning the fiber from a spinning sol whose viscosity is from about 1,000 to below 100,000 mPas. Claims 16, 18 and 19 specify a method for adjusting a biodegradation rate of a silica fiber spun from a silica sol by controlling the viscosity of the spinning sol from about 1,000 to below 100,000 mPas. Claims 20-23 define a

method for adjusting a biodegradation rate of a silica fiber which comprises controlling the viscosity of the silica sol at the starting point of the spinning process. Claims 30-33 are directed to a controllably biodegradable silica fiber spun from silica sol, a biodegradation rate of the fiber being adjusted by either controlling the starting point of the spinning process by a viscosity of the silica sol wherefrom the fibre is spun, or by controlling the viscosity of the spinning sol, the solubility of the fiber in simulated body fluid being 0.2 to 20 weight percent/hour. Claims 24-27 are directed to a delivery device and pharmaceutical preparation containing the controllably biodegradable silica fiber of claim 30. Claims 28 and 29 recite a method for administering a biologically active agent to a human or animal which employs a delivery device comprising a controllably biodegradable device of claim 30.

German patent DE 196 09 551 ("German '551") is discussed in this application (Specification, page 2, lines 9-15) and was made of record in an IDS filed December 4, 2001. Applicants petitioned to withdraw the application from allowance immediately after realizing that German '551 was more relevant to the claimed controllably biodegradable silica fiber than previously believed.

A Transmittal of Partial Translation is attached, and submits excerpts of German '551 believed relevant to the claimed fiber. German '551 discloses the preparation of fibers having a degradation rate of between 10 and 100 nm fiber radius per day, with the degradation rate correlating with the amount of silanol groups on the fiber. German '551 teaches that the biodegradability of silica fibers can be controlled based on the degree or extent of polycondensation. More specifically, a smaller degree of polycondensation results in a greater number of remaining OH-groups, which is taught to result in a higher degradation rate of the resulting fibers. The 10 to 100 nm fiber radius per day degradation rate results in a 50 to 500 day fiber degradation time period.

1. German '551 Fails to Disclose or Suggest the Claimed Methods

German '551 fails to disclose or suggest that controlling the viscosity of a spinning solution from which the fiber is spun can permit adjustment of the biodegradability of the fiber. In this regard, spinning sol viscosity is not dependent on the degree of polycondensation of silica fiber. Instead, polymerisation of SiO₂ gels proceeds on two levels, by polycondensation and by aggregation

of colloidal particles formed by polycondensation. The aggregation behavior of colloidal particles is the main factor controlling the size and form of the aggregates presence in the sol and, thus, also its viscosity.

2. German '551 Fails to Disclose or Suggest the Claimed Fiber

The claimed fiber has a solubility in simulated body fluid being 0.2 to 20 weight percent/hour. The lower (slower) dissolution limit will result in complete fiber dissolution in about 21 days.¹ In contrast, German '551 discloses a fiber whose fastest dissolution time is 50 days.

One of ordinary skill in the art is given no disclosure or suggestion to modify the fiber of German '551 so as to achieve a solubility in simulated body fluid of from 0.2 to 20 weight percent/hour by adjusting or controlling the spinning solution's viscosity from about 1000 to below 100,000 mPas, either at the start or the spinning process or during spinning.

It is not believed any fee is required for entry and consideration of these Supplemental Remarks. Nevertheless, the

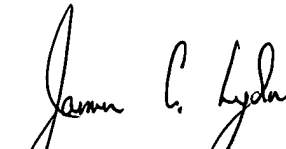
¹(100 weight %)÷(0.20 weight %/hour)(24 hours/day) = 20.8 days.

U.S. Appln. S.N. 09/913,643
SUPPLEMENTAL REMARKS

PATENT

Commissioner is authorized to charge our Deposit Account No. 50-1258 in the amount of any such required fee.

Respectfully submitted,



James C. Lydon
Reg. No. 30,082

Attorney Case No.: TUR-115
100 Daingerfield Road
Suite 100
Alexandria, Virginia 22314
Telephone: (703) 838-0445
Facsimile: (703) 838-0447

Enclosure:
Transmittal of Partial Translation